



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2017-0447; FRL-9971-19]**

**Methyl Bromide; Pesticide Tolerances for Emergency Exemptions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of the fumigant methyl bromide, including its metabolites and degradates in or on post-harvest imported/domestic agricultural commodities. This action is in response to EPA's granting quarantine exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on specified agricultural commodities. This regulation establishes a maximum permissible level for residues of methyl bromide in or on these commodities. The time-limited tolerances expire on December 31, 2020.

**DATES:** This regulation is effective *[insert date of publication in the Federal Register]*.

Objections and requests for hearings must be received on or before *[insert date 60 days after date of publication in the Federal Register]*, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0447, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to

4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0447 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0447, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Background and Statutory Findings**

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for residues of methyl bromide, in or on the following agricultural commodities: Avocado at 5.0 parts per million (ppm); Banana at 5.0 ppm; Cactus at 3.0 ppm; Coconut, copra at 8.0 ppm; Coffee, green bean at 150 ppm; Cola at 150 ppm; Cucurbit, seed at 150 ppm; Fig at 10 ppm; Fruit, berry and small fruit, group 13-07 at 5.0 ppm; Fruit, stone, group 12-12 at 5.0 ppm; Herbs and spices, group 19 at 35 ppm; Hibiscus, seed at 150 ppm; Ivy gourd at 5.0 ppm; Kaffir lime, leaves at 0.50 ppm; Kenaf, seed at 150 ppm; Longan at 5.0 ppm; Lychee at 5.0 ppm; Oilseed group 20 at 150 ppm; Peppermint, tops at 35 ppm; Pointed gourd at 5.0 ppm; Pomegranate at 5.0 ppm; Rambutan at 5.0 ppm; Spanish Lime 5.0 ppm; Spearmint, tops at 35 ppm; Stalk, stem and leaf petiole vegetable group 22 at 0.50 ppm; Tropical and subtropical fruits, edible peel, group 23 at 10.0 ppm; Tropical and subtropical fruits, inedible peel, group 24 at 5.0 ppm; Vegetable, Head and Stem *Brassica*, group 5-16 at 1.0 ppm; Vegetable, bulb, group 3-07 at 2.0 ppm; Vegetable, cucurbit, group 9 at 5.0 ppm; Vegetable, foliage of legume, group 7 at 0.50 ppm; Vegetable fruiting, group 8-10 at 7.0 ppm; Vegetable, leafy, group 4-16 at 0.50 ppm; Vegetable leaves of root and tuber, group 2 at 0.50 ppm; Vegetable, legume, group 6 at 3.0 ppm; Vegetable, root and tuber, group 1 at 3.0 ppm. These time-limited tolerances expire on December 31, 2020.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

### **III. Emergency Exemptions for Methyl Bromide on Various Commodities and FFDCA Tolerances**

Quarantine exemptions were issued to the Plant Protection and Quarantine (PPQ) division of the United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA/APHIS), for the post-harvest use of the fumigant methyl bromide on imported and domestic commodities to target invasive, non-indigenous quarantine plant pests and to prevent the introduction and/or spread of any new or recently introduced foreign pest(s) to any U.S. geographical location.

After having reviewed the submissions, EPA determined that emergency conditions existed for the PPQ division of the USDA/APHIS, and that the criteria for approval of these quarantine exemptions were met. EPA authorized quarantine exemptions under FIFRA section 18 for the post-harvest use of methyl bromide in or on specified imported and domestic agricultural commodities to eliminate the threat of invasive plant pests.

As part of its evaluation of the proposed quarantine emergency uses, EPA assessed the potential risks presented by residues of methyl bromide in or on specified imported and domestic agricultural commodities. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary time-limited tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the quarantine exemption actions in order to address urgent non-routine situations and to ensure that the resulting food is safe and lawful, EPA issued these time-limited tolerances without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2020, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on the specified agricultural commodities after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under

FIFRA, and the residues do not exceed levels that were authorized by these time-limited tolerances at the time of the applications. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether methyl bromide meets FIFRA's registration requirements for use on the specified agricultural commodities or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these time-limited tolerance decisions serve as a basis for registration of methyl bromide by a State for special local needs under FIFRA section 24(c). Nor do these tolerances by themselves serve as the authority for persons other than certified fumigators to use this pesticide on the applicable crops under FIFRA section 18 absent the authorization of the quarantine exemption issued to the Plant Protection and Quarantine division of the United States Department of Agriculture, Animal and Plant Health Inspection Service. For additional information regarding the quarantine exemptions for methyl bromide, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration

to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of these quarantine exemption requests and the time-limited tolerances for residues of methyl bromide on the specified agricultural commodities. EPA's assessment of exposures and risks associated with establishing these time-limited tolerances follows.

#### *A. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health->

*risk-pesticides*. Further, the Agency's exposure and risk assessment for the emergency use of methyl bromide on various agricultural commodities is discussed in greater detail in the following documents: *Methyl Bromide. Section 18 Emergency Quarantine Exemption Use on commodities Requested by the U.S. Department of Agriculture/Animal and Plant Health Inspection Service/Plant Protection and Quarantine (USDA/APHIS/PPQ) Division, May 02, 2017* and *Methyl Bromide: Human Health Risk Assessment for the Section 18 Emergency Exemption Use on USDA APHIS PPQ Commodities, September 13, 2013* are available in the docket at the address provided under **ADDRESSES**. A summary of the toxicological endpoints for methyl bromide used for human risk assessment is shown below in Table 1 of this unit.

Table 1. Summary of Toxicological Doses and Endpoints for Methyl Bromide for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-50 years of age)	Dev. NOAEL = 14 mg/kg/day UF = 100x FQPA SF = 1x	Acute RfD = 0.14 mg/kg/day  aPAD = 0.14 mg/kg/day	Developmental Toxicity - Rabbit (Inhalation)  LOAEL = 28 mg/kg/day based on agenesis of the gall bladder and increased incidence of fused sternebrae.

Acute dietary (General population including infants and children)	NOAEL = 90 mg/kg/day UF = 100x FQPA SF = 1x	Acute RfD = 0.9 mg/kg/day  aPAD = 0.9 mg/kg/day	Acute neurotoxicity study --rat (Inhalation)  LOAEL = 314 mg/kg/day based on decreased activity, increase in number of animals with drooping/half-closed eyelids and alertness as measured in the Functional Observational Battery (FOB), decreased rears, decreased motor activity, increased piloerection and decreased body temperature.
Chronic dietary (All populations)	NOAEL= 2.2 mg/kg/day UF = 100x FQPA SF = 1x	Chronic RfD = 0.022 mg/kg/day  cPAD = 0.022 mg/kg/day	Chronic/carcinogenicity study – rats  LOAEL = 11.1 mg/kg/day based on based on decreased body weight, body weight gain and food consumption.
Cancer (Oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to humans.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF =uncertainty factor.

#### *B. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to methyl bromide, EPA considered exposure under the time-limited tolerances established by this action as well as all existing methyl bromide tolerances in 40 CFR 180.124.

EPA assessed dietary exposures from methyl bromide in food as follows:

i. *Acute exposure.* Acute effects were identified for methyl bromide. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We

Eat in America (NHANES/WWEIA). For purposes of this acute exposure assessment, EPA calculated residue levels based on dissipation and time-to-market data, assumed 100 percent crop treated (PCT) and assumed that no residues were present in any processed commodity where heating was involved.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 NHANES/WWEIA. To estimate chronic exposure from residues in food, EPA calculated residue levels based on dissipation and time-to-market data, assumed 100% crop treated, and assumed that no residues were present in any processed commodity where heating was involved. For the chronic exposure assessment, consumption data were averaged for the entire U.S. population and within population subgroups.

iii. *Cancer.* Based on the data summarized in Unit IV.A., Table 1, EPA has concluded that methyl bromide does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

EPA reviewed numerous residue trials submitted by industry (controlled fumigation trials) in support of the reregistration of methyl bromide. Residue levels were calculated using residue decline curves for each commodity assuming first order kinetics and taking into account minimum predicted time intervals between fumigation and market availability. USDA APHIS requested uses on additional crops, providing detailed use pattern data. For these crops, residue levels were translated from similar commodities having residue trial data, considering use patterns and taking into account time intervals between fumigation and market availability.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for methyl bromide in drinking water. These simulation models take into account data on the physical, chemical, and

fate/transport characteristics of methyl bromide. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

The methyl bromide Estimated Drinking Water Concentration was derived from groundwater estimates. Based on data from the database of pesticides in groundwater (U.S. EPA, 1992), two wells in California (out of 20,429 wells monitored in Florida, California, and Hawaii) had methyl bromide levels of 2.5 and 6.4 microgram/Liter ( $\mu\text{g/L}$ ). The highest groundwater monitoring value of 6.4 parts per billion (ppb) was used for both the acute and chronic (non-cancer) assessments. Concentrations of methyl bromide in surface water are considered negligible due to the rapid dissipation of methyl bromide from water to the air (half-life of 73 minutes).

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Methyl bromide is a restricted use pesticide and is not registered for any specific residential use patterns; however, there is potential for residential bystander inhalation exposure in and around port areas where post-harvest commodity fumigation treatments takes place. Buffers have been implemented on all methyl bromide labels, which reduce bystander exposures to levels that do not exceed the Agency’s level of concern.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at:

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found methyl bromide to share a common mechanism of toxicity with any other substances, and methyl bromide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that methyl bromide does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *C. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of increased quantitative or qualitative susceptibility was observed in developmental toxicity studies in rats or rabbits. The

rabbit inhalation developmental study also did not indicate susceptibility to the young as the dams and the offspring had identical NOAEL and LOAEL values.

Therefore, toxicity studies on adults will not underestimate the risks methyl bromide poses to children.

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for methyl bromide is complete.
- ii. There is no indication that methyl bromide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that methyl bromide results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies. In the rat developmental inhalation study there was no indication of susceptibility to the young, at doses up to 70 ppm. The rabbit inhalation developmental study also did not indicate susceptibility to the young, as the dams and the offspring had identical NOAEL and LOAEL values.
- iv. There are no residual uncertainties identified in the exposure databases. The use of inhalation studies to assess dietary risks is a conservative (protective) approach since inhalation exposure is expected to lead to a higher internal dose than dietary exposure since chemicals will enter the circulatory system before many of the detoxification processes associated with oral exposure (e.g. first pass effect) occur. Therefore, these assessments will not underestimate the exposure and risks posed by methyl bromide.

*D. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD) presented in Unit IV.A. Table 1. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs in Table 1 to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in Unit IV.B. for acute exposure, the acute dietary exposure from food and water to methyl bromide will occupy 3.5% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure. The Agency has determined that dietary risk estimates for aggregate acute exposure through food and water to methyl bromide are below the Agency's level of concern for the U.S. population and all population subgroups. There is also potential for inhalation exposure to residential bystanders. However, since the dietary contribution to acute aggregate risk is negligible, EPA has determined that the mitigation measures EPA required in the 2006 Tolerance Reassessment and Risk Management Decision (TRED) for Methyl Bromide, and Reregistration Eligibility Decision (RED) for Methyl Bromide's Commodity Uses to protect residential bystanders will ensure that acute aggregate risks do not exceed EPA's level of concern.

2. *Chronic risk.* Using the exposure assumptions described in Unit IV.B. for chronic exposure, EPA has concluded that chronic exposure to methyl bromide from food and water will utilize 43% of the cPAD for (children 1-2 years old) the population group receiving the greatest exposure. Based on the explanation in the unit regarding residential use patterns, chronic residential exposure to residues of methyl bromide is not expected. Although there is potential for inhalation exposure to residential bystanders, EPA did not aggregate short-, intermediate-term, or chronic dietary and inhalation exposures to methyl bromide because endpoints for dietary and inhalation exposures for these durations are not based on common toxicological

effects. Methyl bromide is not registered for use in residential settings; therefore, residential exposures from the direct use of methyl bromide in residential areas is not expected.

3. *Short-term risk.* Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Methyl bromide is not registered for use in residential settings; therefore, residential handler exposures from the direct use of methyl bromide in residential areas is not expected. EPA did not aggregate short-, intermediate-term, or chronic dietary and inhalation exposures to methyl bromide because endpoints for dietary and inhalation exposures for these durations are not based on common toxicological effects.

4. *Intermediate-term risk.* Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Methyl bromide is not registered for use in residential settings; therefore, residential handler exposures from the direct use of methyl bromide in residential areas is not expected. EPA did not aggregate short-, intermediate-term, or chronic dietary and inhalation exposures to methyl bromide because endpoints for dietary and inhalation exposures for these durations are not based on common toxicological effects.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, methyl bromide is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to methyl bromide residues.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An adequate enforcement methodology (King headspace method, J. Agricultural Food Chemistry, Vol 29, No. 5, pp 1003-1005) is available to enforce the tolerance expression. This method is a gas chromatography/electron capture (GC/EC) method that was validated in 1987 in the EPA Environmental Chemistry Laboratory (D168869, L. Cheng, 27-OCT-1992). The headspace procedure for determining methyl bromide has been forwarded to FDA for inclusion in PAM Vol. II. This method is adequate for data collection and for tolerance enforcement on plant and processed food commodities.

#### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Methyl bromide Codex MRLs have been established for several commodities; however, there are no Codex MRLs for any of the commodities that are the subject of this quarantine action. Therefore, at this time, there are no harmonization issues.

#### **VI. Conclusion**

Therefore, time-limited tolerances are established for residues of the fumigant methyl bromide, including its metabolites and degradates, in or on specified agricultural imported/domestic commodities. These tolerances expire on December 31, 2020.

## **VII. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct

effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

#### **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 13, 2018.

Donna S. Davis,  
*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In §180.124, revise paragraph (b) to read as follows:

**§ 180.124 Methyl bromide; tolerances for residues.**

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances as listed in the following table are established for residues of the fumigant methyl bromide, including its metabolites and degradates, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified below is to be determined by measuring only methyl bromide. These tolerances expire and are revoked on the date indicated in the table.

Commodity	Parts per million	Expiration date
Avocado	5.0	December 31, 2020
Banana	5.0	December 31, 2020
Cactus	3.0	December 31, 2020
Coconut, copra	8.0	December 31, 2020
Coffee, green bean	150	December 31, 2020
Cola	150	December 31, 2020
Cucurbit, seed	150	December 31, 2020
Fig	10	December 31, 2020
Fruit, berry and small fruit, group 13-07	5.0	December 31, 2020
Fruit, stone, group 12-12	5.0	December 31, 2020
Herb and spice, group 19	35	December 31, 2020
Hibiscus, seed	150	December 31, 2020
Ivy gourd	5.0	December 31, 2020
Kaffir lime, leaves	0.50	December 31, 2020

Kenaf, seed	150	December 31, 2020
Longan	5.0	December 31, 2020
Lychee	5.0	December 31, 2020
Oilseed group 20	150	December 31, 2020
Peppermint, tops	35	December 31, 2020
Pointed gourd	5.0	December 31, 2020
Pomegranate	5.0	December 31, 2020
Rambutan	5.0	December 31, 2020
Spanish lime	5.0	December 31, 2020
Spearmint, tops	35	December 31, 2020
Stalk, stem and leaf petiole vegetable group 22	0.50	December 31, 2020
Tropical and subtropical fruits, edible peel, group 23	10	December 31, 2020
Tropical and subtropical fruits, inedible peel, group 24	5.0	December 31, 2020
Vegetable, bulb, group 3-07	2.0	December 31, 2020
Vegetable, cucurbit, group 9	5.0	December 31, 2020
Vegetable, foliage of legume, group 7	0.50	December 31, 2020
Vegetable, fruiting, group 8-10	7.0	December 31, 2020
Vegetable, Head and Stem <i>Brassica</i> , group 5-16	1.0	December 31, 2020
Vegetable, leafy, group 4-16	0.50	December 31, 2020
Vegetable, leaves of root and tuber, group 2	0.50	December 31, 2020
Vegetable, legume, group 6	3.0	December 31, 2020
Vegetable, root and tuber, group 1	3.0	December 31, 2020

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